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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,471	08/27/2001	William J. Rissmann	032580.0018.UTL	5252

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EXAMINER

MULLEN, KRISTEN DROESCH

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 07/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/940,471

Applicant(s)

RISSMANN ET AL.

Examiner

Kristen Mullen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/25/05 (Response).
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) _____ is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 195,203-206,209-211 and 213-217 is/are allowed.
- 6) ☒ Claim(s) 192-194,196-198,200 and 208 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 2/6/04 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 208 is rejected under 35 U.S.C. 102(b) as being anticipated by KenKnight (6,148,230). A method comprising providing a lead assembly including a first electrode (22, 24) implanted in a patient, the lead assembly provided such that it does not contact the patient's heart; providing a device including a battery and a means for storing energy, the device being coupled to the lead assembly; providing a second electrode (18) implanted such that it does not contact the patient's heart; sensing far-field signals using a sensing electrode pair including the first electrode (22, 24) to monitor a portion of the patient's cardiac rhythm; determining whether the patient's cardiac rhythm requires electrical therapy; and, if so: supplying energy from the battery to the energy storage means; and discharging energy stored in the energy storage means to the patient using a stimulus electrode pair including the second electrode (11); wherein the second electrode is provided on a housing of the device (Fig. 1) and wherein the step of providing the lead assembly includes extending the lead assembly medially from the device.

With respect to the lead extending medially from the device, see Fig. 2 of 5,314,430 which is incorporated by reference and shows the leads extending medially (from the middle of the width) of the device.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 192-194 and 196-198 are rejected under 35 U.S.C. 103(a) as being unpatentable over Causey III (5,411,547) in view of Bennett et al. (5,331,966).

With respect to claim 193, Causey III shows a method of supplying energy for alleviating a cardiac dysfunction comprising: implanting a device having a power source and an energy storage system into a patient; providing a lead system having one or more electrodes, the lead system provided such that it is disposed internally to a patient without contacting the patient's heart; coupling the power source to the energy storage system; storing energy in the energy storage system; and discharging the energy from the energy storage system to the patient, the step of discharging the energy including using at least one electrode (24, 26) disposed in the lead system; wherein the step of sensing an abnormality further includes determining whether the patient has an abnormally slow heart rate (asystole) (Col. 1, lines 36-39; Col. 3, lines 28-53) (Fig. 4). Although Causey III fails to show sensing an abnormality in the patient's rhythm using electrodes disposed internally to the patient but not contacting the patient's heart, attention is directed to Bennett et al. which teaches an implantable stimulus device with electrodes located on the device housing to sense arrhythmias. Bennett teaches that providing multiple sensing electrodes (A, B, C) on the device housing provides a leadless orientation insensitive means for receiving electrical signals from the heart (Abs). Therefore, it

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would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the device housing and method of Causey III Adams with the device housing incorporating sensing electrodes as Bennett et al teaches in order to provide a leadless orientation insensitive means for receiving electrical signals from the heart.

Regarding claim 192, Causey III shows providing a lead system such that it does not reside in the patient's vasculature (Fig. 4).

With respect to claims 196-197, Causey III further shows determining if the patient has an abnormally fast heartbeat or determining if the patient is likely experiencing defibrillation (Col. 1, lines 36-39).

Regarding claim 198, Bennett shows the electrodes are part of the lead system (Fig. 2c).

Regarding claim 198, Causey III shows the electrodes (24, 26) are part of the lead system (Fig. 4).

5. Claim 200 is rejected under 35 U.S.C. 103(a) as being unpatentable over Causey, III (5,411,547) in view of Bennett et al. (5,331,966) and further in view of Bardy (5,292,338).

Causey III and Bennett et al. are as explained before. Causey III and Bennett et al. fail to specifically point out that the defibrillator is implanted subcutaneously between the third rib and the twelfth rib of the patient, but only mentions that a known defibrillator is used. Attention is directed to Bardy, which teaches a known defibrillator that is implanted in the left infraclavicular pectoral region. As seen in Fig. 2 of Sanchez, Zambrano (5,895,414) the clavicle (21) is located approximately at the same location or level as the third rib (23) in the pectoral region. Thus, if the known defibrillator of Bardy is implanted in the left infraclavicular pectoral region, it is advanced below the third rib and above the twelfth rib. Therefore, it would have been obvious to

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one with ordinary skill in the art at the time the invention was made to implant the defibrillator of Causey III and Bennett et al. subcutaneously between the third rib and the twelfth rib of the patient as is known for implanting known defibrillators.

Response to Arguments

6. Applicant's arguments filed 4/25/05 have been fully considered but they are not persuasive.

Regarding claims 192-194 and 196-198 and applicants' arguments that the electrodes "near the surface of the heart" of Causey being inaccurate and the electrodes comprising epicardial but non-conforming electrodes is not convincing. In Col. 3, lines 48-53, Causey specifically shows the electrodes "near the surface of the heart" not being in contact with the heart in Fig. 1.

Regarding claim 208 and applicants' arguments that KenKnight does not show the lead assembly extending medially from the device, applicant does not claim the lead extends medially with respect to any location within the body. Medially generally relates to the middle.

Allowable Subject Matter

7. Claims 195, 201-206, 209-211 and 213-217 are allowed.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Mullen whose telephone number is (571) 272-4944. The examiner can normally be reached on M-F, 10:30 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kristen Mullen

kdm


ROBERT E. PEZZUTO
PRIMARY EXAMINER